IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

DOROTHY OAKLEY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CAUSE NO. 1:07-cv-0399-RLY-WTL
	)	
MERCK & CO., INC.,	)	
	)	
Defendant	)	
	)	

ANSWER AND DEFENSES OF MERCK & CO., INC.

Defendant, Merck Co., Inc. ("Merck"), by and through its undersigned attorneys, hereby answers plaintiff's Complaint for Damages ("Complaint"). Merck denies all allegations set forth in the Complaint except to the extent such allegations are specifically admitted below:

RESPONSE TO "I. JURISDICTION AND VENUE"

1. The allegations of the first sentence of Paragraph 1 are conclusions of law to which no response is required. To the extent that a response is required, Merck denies each and every allegation of the first sentence of Paragraph 1. As to the allegations of the second sentence of Paragraph 1, Merck is without knowledge or information sufficient to form a belief as to these allegations, except that Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey. As to the allegations in the third sentence of Paragraph 1, Merck admits for jurisdictional purposes only, that Plaintiff seeks in excess of $75,000.

2. The allegations of the first sentence of Paragraph 2 are conclusions of law to which no response is required. To the extent a response is required, Merck denies the allegations in the first sentence of Paragraph 2. Merck denies each and every allegation in the second

sentence of Paragraph 2 except Merck admits that it does business in this district and throughout the United States.

RESPONSE TO "II. PARTIES"

3. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 3.

4. Merck admits the allegations of Paragraph 4.

5. Merck admits that it is registered to do business in the State of Indiana.

6. Merck is without knowledge as to what is meant by the phrase "regularly transacted" and therefore denies each and every allegation of Paragraph 6 except that Merck admits that it does business in Indiana and throughout the United States.

7. Merck denies each and every allegation of Paragraph 7, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 7 inconsistent with that prescribing information and respectfully refers the Court to the Physician's Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

8. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 8 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 8.

9. Merck is without knowledge as to what is meant by the phrase "substantial revenue," so the allegations in Paragraph 9 are denied.

10. Merck is without knowledge as to what is meant by "consequences," so the allegations in Paragraph 10 are denied.

11. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 11 inconsistent with that prescribing information. Except as expressly admitted herein, Merck denies the remaining allegations of Paragraph 11.

RESPONSE TO "III. SUMMARY OF THE CASE"

12. Merck denies each and every allegation of Paragraph 12, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

13. Merck denies each and every allegation of Paragraph 13.

14. Merck denies each and every allegation of Paragraph 14.

15. Merck denies each and every allegation of Paragraph 15.

16. Merck denies each and every allegation of Paragraph 16.

RESPONSE TO "IV. FACTUAL BACKGROUND"

17. Merck denies each and every allegation of Paragraph 17, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

18. Merck denies each and every allegation of Paragraph 18, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies

any allegations in Paragraph 18 inconsistent with that prescribing information. Merck further admits that FOSAMAX® is the brand name for alendronate

19. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 19 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 19 with respect to Aredia and Zometa inconsistent with that prescribing information.

20. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 20 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 20 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 20.

21. Merck denies each and every allegation of Paragraph 21.

22. Merck denies each and every allegation of Paragraph 22.

23. Merck denies each and every allegation of Paragraph 23.

24. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31.

32. Merck denies each and every allegation of Paragraph 32.

33. Merck denies each and every allegation of Paragraph 33, except that Merck admits that Fosamax product sales in 2005 amounted to approximately $3.19 billion.

34. Merck is without knowledge as to whether Plaintiff used FOSAMAX®. Merck denies the remaining allegations in Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck is without knowledge as to whether Plaintiff was prescribed FOSAMAX®. Merck denies the remaining allegations in Paragraph 36.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 38.

39. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.

44. Merck denies each and every allegation of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

RESPONSE TO "COUNT I: NEGLIGENCE"

46. Merck repleads its answers to Paragraphs 1 through and including 45, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

47. The allegations in Paragraph 47 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

48. Merck denies each and every allegation of Paragraph 48, including each and every allegation contained in subparts (a) through (f).

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

RESPONSE TO "COUNT II: STRICT LIABILITY"

51. Merck repleads its answers to Paragraphs 1 through and including 50, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

52. Merck denies each and every allegation of Paragraph 52, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

53. Merck denies each and every allegation of Paragraph 53, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

54. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 54.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56.

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck denies each and every allegation of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

RESPONSE TO "COUNT III: BREACH OF EXPRESS WARRANTY"

63. Merck repleads its answers to Paragraphs 1 through and including 62, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

64. Merck denies each and every allegation of Paragraph 64, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. Merck denies each and every allegation of Paragraph 69.

RESPONSE TO "COUNT IV: BREACH OF IMPLIED WARRANTY"

70. Merck repleads its answers to Paragraphs 1 through and including 69, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

71. Merck denies each and every allegation of Paragraph 71, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

72. Merck denies each and every allegation of Paragraph 72, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

73. Merck denies each and every allegation of Paragraph 73.

74. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 74.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 76.

77. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

79. Merck denies each and every allegation of Paragraph 79.

RESPONSE TO "COUNT V: FRAUDULENT MISREPRESENTATION"

80. Merck repleads its answers to Paragraphs 1 through and including 79, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

81. Merck denies each and every allegation of Paragraph 81, including each and every allegation contained in subparts (a) through (b).

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

86. Merck denies each and every allegation of Paragraph 86.

87. Merck denies each and every allegation of Paragraph 87.

88. Merck denies each and every allegation of Paragraph 88.

RESPONSE TO "COUNT VI: FRAUDULENT CONCEALMENT"

89. Merck repleads its answers to Paragraphs 1 through and including 88, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

90. Merck denies each and every allegation of Paragraph 90, including each and every allegation contained in subparts (a) through (b).

91. Merck denies each and every allegation of Paragraph 91.

92. Merck denies each and every allegation of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

RESPONSE TO "COUNT IX: PUNITIVE DAMAGES"
[This count is numbered incorrectly. The Complaint does not include a Count VII or Count VIII.]

97. Merck repleads its answers to Paragraphs 1 through and including 96, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99, except that it admits that Merck scientists participated in the VIGOR study involving Vioxx®, published in the New England Journal of Medicine, and respectfully refers the Court to the referenced study for its actual conclusions and full text.

100. Merck denies each and every allegation of Paragraph 100, except that it admits that Merck received a letter from Thomas W. Abrams of DDMAC in September 2001 and respectfully refers the Court to that letter for its actual language and full text.

101. Merck denies each and every allegation of Paragraph 101.

102. Merck denies each and every allegation of Paragraph 102, except that it admits that on August 26, 2004, Merck issued a press release regarding the conclusions of a study presented at the 20th International Conference of Pharmacoepideminology & Therapeutic Risk

Management and respectfully refers the Court to that press release for its actual language and full text.

103. Merck denies each and every allegation of Paragraph 103, except that it admits that the referenced study exists and respectfully refers the Court to said study for its actual language and full text. Merck further admits that on September 30, 2004, Merck announced that in a prospective, randomized, placebo-controlled clinical trial there was an increased relative risk for confirmed cardiovascular events beginning after 18 months of treatment in the patients taking Vioxx compared with those taking placebo, and that, given the availability of alternative therapies and questions raised by the data from that trial, Merck concluded that a voluntary withdrawal of Vioxx best served the interests of patients.

104. Merck denies each and every allegation of Paragraph 104.

105. Merck denies each and every allegation of Paragraph 105.

Merck denies that Plaintiff is entitled to any of the relief requested in her Wherefore clause.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

DEFENSES

Discovery and investigation may reveal that any one or more of the following defenses should be available to Merck in this matter. Merck, therefore, asserts said defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims

and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

FIRST DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

THIRD DEFENSE

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

EIGHTH DEFENSE

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault codified at Ind. Code § 34-51-2-1 *et seq*.

NINTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

TENTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH DEFENSE

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity and/or because the alleged warranties were disclaimed.

FOURTEENTH DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

FIFTEENTH DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SIXTEENTH DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

SEVENTEENTH DEFENSE

Plaintiffs claims are barred in whole or in part because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

EIGHTTEENTH DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

NINETEENTH DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTIETH DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-FIRST DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-THIRD DEFENSE

Plaintiff's claims are barred in whole or in part by failure to prevent or mitigate the damages claimed.

TWENTY-FOURTH DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Indiana Constitutions.

TWENTY-FIFTH DEFENSE

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

TWENTY-SIXTH DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

TWENTY-SEVENTH DEFENSE

Plaintiff has not suffered any actual injury or damages.

TWENTY-EIGHTH DEFENSE

Plaintiff's claimed are barred under the doctrine of economic loss.

TWENTY-NINTH DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTIETH DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-FIRST DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens.*

THIRTY-SECOND DEFENSE

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiffs for any amounts received from collateral sources.

THIRTY-THIRD DEFENSE

To the extent that Plaintiffs asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

THIRTY-FOURTH DEFENSE

To the extent that Plaintiff relies upon any theory of fraud, Plaintiff's claims are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Federal Rule of Civil Procedure 9(b).

THIRTY-FIFTH DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, be subject to the limitations of Ind. Code § 34-51-3-1 *et seq.*

THIRTY-SIXTH DEFENSE

Merck reserves its right to assert a "non-party defense" under Indiana law.

In so much as the complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable

rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

Respectfully submitted,

PLEWS SHADLEY RACHER & BRAUN LLP

s/ Brett E. Nelson
Attorneys for Defendant Merck & Co., Inc.

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CERTIFICATE OF SERVICE

I hereby certify that on April __, 2007 a copy of the foregoing was electronically served upon the following via the CM/ECF system:

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